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## REMARKS

In response to the Office Action dated February 12, 2008, Applicant respectfully requests reconsideration. Applicant has not amended any of the claims. Claims 12-37 remain pending.

### Objections to the Claims

In the current Office Action, the Examiner objected to all pending claims, and indicated that the following phrase is unclear:

> wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility

According to the Examiner, it is not clear from this language whether "health care delivery practices" or "surgical procedures" are "selectable." Applicant disagrees with this objection.

There is only one correct way to read the phrase in question consistent with English grammar rules. That is, the verb phrase "are selectable" modifies the subject "health care delivery practices." It would be incorrect grammar to assert that "are selectable" modifies "the surgical procedure." The phrase "surgical procedure" is the object of the prepositional phrase "with the surgical procedure," and is not the subject that is modified by "are selectable."

The only way to read the phrase above according to English grammar is to read the verb phrase "are selectable" as modifying "health care delivery practices." In other words, the claim requires the health care delivery practices (i.e., those "associated with the surgical procedure that pose a source of measurable risk of surgical site infection") to be selectable for a given health care facility.

Put another way, "associated with the surgical procedure are selectable" is not a sentence, "with the surgical procedure are selectable" is not a sentence, and "surgical procedure are selectable," is grammatically incorrect. It is impossible to read "are selectable" as modifying "the surgical procedure" in a way that conforms to proper English grammar. The only way to read the phrase above according to English grammar is to require the verb phrase "are selectable" to modify the subject "health care delivery practices."

Withdrawal of the claim objections is courteously requested.

## The Pending Independent Claims

Independent claim 12 recites a computer-implemented system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the computer-implemented system comprising software that identifies a plurality of stages of operative care associated with the surgical procedure, including at least a preoperative stage, an intraoperative stage and a postoperative stage, identifies one or more points-of-care within each identified stage of operative care associated with the surgical procedure, for each point-of-care associated with the surgical procedure, identifies one or a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection, wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility, identifies one or more compliance indicators associated with the surgical procedure for the one or plurality of health care delivery practices associated with the surgical procedure within each point-of-care associated with the surgical procedure whereby there is provided the ability to monitor the compliance indicators, wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices, and for each of the compliance indicators, generates a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby align the health care delivery practices associated with the surgical procedure into rule compliance and to provide a perioperative process map of delivery practices spanning the plurality of stages of operative care associated with the surgical procedure to thereby manage the risk or occurrence of surgical site infection incident to the surgical procedure.

Independent claim 13 recites a system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the system comprising a perioperative process map of practices for the delivery of the surgical procedure, the map comprising a plurality of health care delivery practices associated with the surgical procedure and one or more indicators of compliance with the one or more health care practices, wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility, and wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding

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health care practices. The system of claim 13 further comprises means for monitoring the compliance indicators to achieve a desired level of management of the risk of surgical site infection for the surgical procedure, wherein the means for monitoring the compliance indicators generates a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure.

Independent claim 22 recites a computer-implemented method for managing risks of surgical site infection incident to a surgical procedure. The method of claim 22 comprises selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection, evaluating a given one of the practices associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure, storing data indicative of the given practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure, and identifying via a compliance indicator when the data indicative of the given practice associated with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure, wherein the compliance indicator quantifies a measure of quality associated with delivery of the given practice.

Independent claim 37 recites a computer-implemented system for managing risks of surgical site infection incident to a surgical procedure. The system comprises means for selecting for a given health care facility a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection, means for evaluating a given one of the practices associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure, means for storing data indicative of the given practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure, and means for identifying via a compliance indicator when the data indicative of the given practice associated with the surgical procedure is not in compliance with a rule established for the given practice to thereby manage risks of surgical site infection incident to the surgical procedure, wherein the compliance indicator quantifies a measure of quality associated with delivery of the given practice.

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### Previous Arguments

Applicant hereby incorporates all of the previous arguments advanced in Applicant's response of January 23, 2008. Applicant remains unconvinced by the Examiner's analysis, and submits that rejections based on the prior art combinations of Mangram, Ormond-Walshe, Blume and Mushabac, will not be upheld if Applicant is forced into an Appeal. Applicant filed an RCE at the Examiner's request (see the Examiner's suggestion in the Office Action mailed June 5, 2007) and attempted to modify the claims specifically to address the Examiner's concerns. However, the Examiner is now applying additional references (namely the Sullivan and Afsah references), which appear to have little or no relevance to the systems and features that Applicant is attempting to patent. The newly cited Sullivan and Afsah references are addressed under a separate heading below.

In order to preserve argument for Appeal, Applicant submits the following, which addresses the Examiner's application of the Mangram, Ormond-Walshe, Blume and Mushabac references. Again, the newly cited Sullivan and Afsah references are addressed under a separate heading below. Given the numerous problems with the Examiner's combination of Mangram, Ormond-Walshe, Blume and Mushabac, as well as the deficiencies of Sullivan and Afsah addressed below, Applicant respectfully submits that the Examiner's analysis is clearly based on hindsight. Of course, it is impermissible in an obviousness analysis for the Examiner to reconstruct Applicant's claimed invention based on hindsight.

In the Examiner's analysis, the Examiner cited Mangram as teaching techniques for managing risks of surgical site infection in a surgical procedure. The Examiner recognized that Mangram fails to suggest a computer-implemented system for managing such risks, but cited Ormond-Walshe as teaching the use of computerized databases in the medical field. The Examiner argued that a person of ordinary skill in the art would have been motivated to implement the computerized databases of Ormond-Walshe to manage the risks of surgical site infection taught by Mangram.

Applicant disputes the Examiner's conclusion that a person of ordinary skill in the art would have modified the teaching of Mangram in view of Ormond-Walshe to implement compliance indicators associated with the surgical procedure for one or a plurality of health care

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practices associated with the surgical procedure. Applicant also disputed this conclusion several times previously, but the Examiner has failed to address these arguments, e.g., claiming that the arguments were moot in view of the new grounds of rejection. Applicant's arguments that a person of ordinary skill in the art would not have modified the teaching of Mangram in view of Ormond-Walshe are applicable to the current claims in the same way that these arguments have been applicable to previous claims. The Examiner's failure to address this argument is improper.

While Mangram may provide a manual guideline for prevention of surgical site infection, this reference lacks any suggestion of compliance indicators associated with the surgical procedure for one or a plurality of health care practices associated with the surgical procedure whereby there is provided the ability to monitor the compliance indicators. Moreover, the vague teaching of Ormond-Walshe concerning the use of computerized databases would have provided no additional insight to a person of ordinary skill in the art regarding the implementation of compliance indicators associated with the surgical procedure. In particular, the broad general discussion of computerized databases for use by infection nurses, per Ormond-Walshe, provides no insight to the specific implementation of compliance indicators associated with the surgical procedure, as recited, e.g., in claims 12 and 13.

In the Examiner's analysis, the Examiner recognized that the combination of Mangram and Ormond-Walshe still fails to disclose or suggest generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule (claims 12 and 13) or identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice (claim 22). However, the Examiner stated that this feature is well known in the art as evidenced by Blume and Mushabac.

However, nothing in Blume, Mushabac or any of the applied references discloses or suggests computer-implemented techniques that generate a flag when a given health care delivery practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13) or techniques that identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22). Moreover, a person of

ordinary skill in the art would not have been motivated to implement the techniques or devices of

Blume and/or Mushabac with the teaching of Mangram or Ormond-Walshe.

The entire passage of Blume relied upon by the Examiner is reproduced below:

> Data received from localizers 20, and the processing by processor 32 to present a
> graphical representation on display 40 of the magnetic field produced by magnet 14 must
> be fast enough to provide "real-time" feedback for a surgeon; i.e., the feedback must be
> rapid enough to allow decisions to be made during a surgical procedure involving the
> movement of the implanted magnetic device 30. The method of Procrustes is used to
> compute the 4.times.4 rigid body transformation between coordinates in the imaging
> system and coordinates in the localizer system. Thereafter, the 4.times.4 matrix may be
> applied to transform a pre-stored representation of a magnetic field into a magnetic field
> having the position and orientation sensed by localizers 20 using standard programming
> techniques on a presently-available Intel PENTIUM.RTM.-based processor (such as a
> typical PC), or a Silicon Graphics workstation, with the transformation being
> accomplished in sufficient time to provide a display that is updated rapidly enough for
> surgical purposes. Column 7, lines 16-33.

Contrary to the Examiner's conclusion, this teaching in Blume has no relevance with respect to

the features recited in Applicant's claims, which concern computer-implemented systems for

managing the risk or occurrence of surgical site infection.  In contrast to Applicant's claims, the

above passage of Blume describes the use of magnets in a surgical procedure to provide the

surgeon with positioning feedback via a display regarding the positioning and movement of an

implanted magnetic device.  Thus, this teaching of Blume has no relevance to

computer-implemented systems for managing the risk or occurrence of surgical site infection,

and lacks any teaching pertinent to such endeavors.

Furthermore, the teaching of Blume cited above clearly lacks any suggestion of

generating a flag when a given health care delivery practice associated with the surgical

procedure is not in compliance with a rule to thereby manage the risk of surgical site infection

incident to the surgical procedure (claims 12 and 13) or identifying when the data indicative of

the practice associated with the surgical procedure is not in compliance with a rule established

for the practice to thereby manage the risk of surgical site infection incident to the surgical

procedure (claim 22).

Similarly, the teaching of Mushabac relied upon by the Examiner is also irrelevant to the

features of Applicant's claims.  The relied upon passage of Mushabac is reproduced below.

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> Advantageously, the computer provides the dental practitioner operating the dental tool with an alert signal regarding deviation between an actual position and orientation of the tool during the use of the tool on the patient and the optimal position and the optimal orientation, as determined prior to the dental operation. The alert signal may take the form of an auditory signal, for example, a verbal message or instruction synthesized by the computer. Alternatively or additionally, the alert signal may include a visual indication provided on the monitor. An alert signal may also be provided in a practice operation, to indicate to the operator a deviation or a conformity of the practice instrument to the predetermined, recommended position and orientation thereof. Column 4, lines 56 to column 5, line 2.

This passage of Mushabac also lacks any relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection. Instead, this passage of Mushabac describes a dental tool that generates an audible or visible alert when the dental tool is mis-positioned.

An alert that is generated when a dental tool is mis-positioned is nothing akin to the features of Applicant's claims, e.g., generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13) or identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22). A person of ordinary skill in the art would not have found any teaching in Mushabac or Blume that would have led the person to modify a computer-implemented system for managing the risk or occurrence of surgical site infection to generate a flag when a surgical procedure is not in compliance with a rule.

Indeed, the teachings of Blume and Mushabac are completely unrelated to those of Mangram and Ormond-Walshe. Accordingly, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Mushabac and Blume. To be sure, Blume describes a system that provides a surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device, and Mushabac describes a dental tool that generates an alert when the tool is mis-positioned. These teachings concern totally different endeavors than those of Mangram and Ormond-Walshe and include no teachings pertinent to the management of infection in surgical procedures.

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Furthermore, even if the alert generation in Mushabac could be reasonably construed as generating a flag, the alert in Mushabac occurs when a dental tool becomes misaligned, and has no relevance to compliance of a surgical procedure with a rule, nor any relevance to the management of risks of surgical site infection incident to the surgical procedure.

In short, Applicant disputes the Examiner's conclusion that a person of ordinary skill in the art would have been motivated to combine the teaching of Mangram and Ormond-Walshe to implement compliance indicators. Neither Mangram nor Ormond-Walshe (either alone or in combination) disclose or suggests this feature.

In addition, neither Mushabac nor Blume discloses or suggests computerized generation of a flag or identification of data associated with a surgical procedure to thereby manage the risk of surgical site infection incident to the surgical procedure. To the extent that Mushabac teaches the generation of an alert, the alert in of Mushabac relates to dental tool misalignment, and has no relevance to a surgical procedure, nor any relevance to the management of risks of surgical site infection incident to the surgical procedure. Furthermore, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Mushabac or Blume. Indeed, positioning of implanted magnetic devices, per Blume, and dental tools that generate alerts when the tools are mis-positioned, per Mushabac, are not reasonably pertinent to the teachings of Mangram concerning prevention of surgical site infection, nor reasonably pertinent to the teaching of Ormond-Walshe concerning computerized databases for infection control. For each of these reasons, the current rejections must be withdrawn.

### The Newly Cited References Applied under 35 U.S.C. § 103

Applicant filed the last response and RCE at the Examiner's request (see the Examiner's suggestion in the Office Action mailed June 5, 2007) and attempted to modify the claims specifically to address the Examiner's concerns. However, the Examiner is now applying additional references (namely the Sullivan and Afsah references), which appear to have little or no relevance to the systems and features that Applicant is attempting to patent.

In addition, Applicant's recent response presented new claims 34-37. New claims 34-36 present features that the Examiner has not considered. However, in the current rejections, the

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Examiner failed to even address claims 34-36, but merely stated that "as per claims 26-37, these claims repeat feature previously rejected in the rejection of claims 12-25 and are rejected on the same basis." This statement by the Examiner is incorrect. Claims 34-36 present new features that the Examiner did not consider in the current Office Action.

In the current Office Action, the Examiner recognized that the combination of Mangram, Ormond-Walshe, Blume and Mushabac (addressed above) fails to suggest "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility" as required by Applicant's claims. For this feature, the Examiner cited Sullivan (specifically "section [0055]") and argued that it would have been obvious to further modify the combination of Mangram, Ormond-Walshe, Blume and Mushabac in view of Sullivan.

Applicant traverses this argument for two reasons. First, the cited passage of Sullivan does not qualify as prior art to Applicant's claims. Second, the cited passage of Sullivan appears to be wholly irrelevant to the feature "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility."

Paragraph [0055] of Sullivan is reproduced below:

> [0055] FIG. 23 is another illustration of a screen display
> of a prescription medicine template.

The Examiner's assertion is implausible. This paragraph of Sullivan in no way suggests any feature even remotely akin to "wherein the health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection are selectable for a given health care facility," as required by Applicant's independent claims.

In addition, paragraph [0055] of Sullivan is not even prior art to Applicant's claims. Sullivan was filed on November 2, 2001, which is after Applicant's filing date of December 4, 2000. While Sullivan claims priority to a provisional application filed on November 2, 2000, the provisional application only includes sixteen figurers. Paragraph [0055] of Sullivan and FIG. 23 are not included in the provisional of Sullivan. Accordingly, to the extent the Examiner relied upon paragraph [0055] and FIG. 23, these cited portions of Sullivan are not entitled to the November 2, 2000 priority date.

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For each of these reasons, the current rejections must be withdrawn.

In the current Office Action, the Examiner also recognized that the combination of Mangram, Ormond-Walshe, Blume, Mushabac and Sullivan fails to suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices." For this feature, the Examiner cited column 6, lines 9-20, of Afsah. Applicant notes that the application for the Afsah patent was filed after Applicant's current application, and that it is unclear whether the relied upon passage of Afsah is entitled to the priority date of Afsah that pre-dates Applicant's case. Since the provisional application of Afsah is not provided in the USPTO's public patent application information retrieval system, Applicant requests that the Examiner provide evidence that this relied upon passage of Afsah is indeed entitled to the priority date.

Regardless of whether Afsah is entitled to the priority date, however, Applicant also notes that the cited passage of Afsah does not disclose or suggest "wherein at least some of the compliance indicators quantify a measure of quality associated with delivery of corresponding health care delivery practices." The passage of Afsah at column 6, lines 9-20 is reproduced below:

> Although the above method for determining the bench-
> 10 mark value of a particular indicator is preferred, there are
> other ways of identifying a benchmark value. For example,
> either the limit value of an indicator mandated by compli-
> ance regulations, or an historical baseline value can be used
> as the benchmark value for an indicator. Also the quartile
> 15 approach can be used where the data group of indicator
> values is divided into quartiles and the worst value from the
> best quartile is selected as the benchmark value. Similarly,
> the best 10% approach can be used where the best 10% of
> the indicator value data group is selected and the worst value
> 20 of the best 10% is designated as the benchmark value.

In this case, the so-called "benchmark value" is a benchmark for air admissions, used to help measure environmental performance. Indeed, Afsah is not even relevant to health care, much less the features of Applicant's claims. The passage above does not suggest any compliance indicator that indicates compliance with the one or more health care delivery practices, as

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required by Applicant's claims, much less a compliance indicator that quantifies a measure of quality associated with delivery of corresponding health care practices.

## CONCLUSION

In view of the numerous arguments above, and numerous problems with the Examiner's current rejections, Applicant respectfully requests reconsideration and prompt allowance of all pending claims.
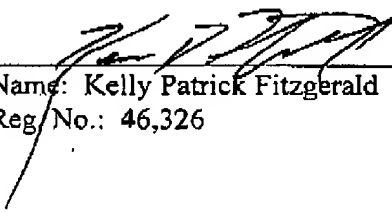
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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